



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER
PROGRAM DISAPPROVAL AND DETENTION

VIA FEDERAL EXPRESS

Mr. Conrad Yin
Manager
Tatung Company of America, Inc.
2850 El Presidio Street
Long Beach, California 90810

Mr. L. S. Ho
General Manager
Tatung Electronics (Wu-Jiang) Company, Ltd.
No. 5 Wu-Tong Road, Song-Ling Town
Wu-Jiang City, Jiangsu,
PEOPLES REPUBLIC OF CHINA

Ref: OC: 11-1945

Dear Messrs. Yin and Ho:

This letter is to notify you that the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), hereby disapproves the microwave oven quality control and testing program for Tatung Electronics (Wu-Jiang) Company, Ltd. (also known as Tatung Home Appliances (Wu-Jiang) Co., Ltd.), located in Wu-Jiang City, Jiangsu, China (hereafter referred to as "Tatung Wu-Jiang" microwave oven factory). This action is taken under the authority of the United States (U.S.) Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C – Electronic Product Radiation Control (hereafter referred to as "the Act").

Based on the inspection findings listed below, CDRH declares that Tatung Wu-Jiang has failed to conduct a testing program which assures compliance of its microwave ovens with the applicable U.S. Federal Performance Standard (21 C.F.R. § 1030.10). CDRH therefore, under the authority of Section 534(h) of the Act and Title 21 of the Code of Federal Regulations (21 CFR) Section 1010.2(c), disapproves the testing and quality control program for all microwave ovens manufactured at Tatung Wu-Jiang effective immediately. In accordance with 21 CFR § 1010.2(c) and the Act, "Such certification shall be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program which is in accordance with good manufacturing practices.

The Director, Center for Devices and Radiological Health, may disapprove such a testing program on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standards prescribed under this subchapter.”

This disapproval of the testing program for microwave ovens means that Tatung Wu-Jiang microwave oven factory is prohibited by Sections 534(h) and 538 of the Act from:

1. certifying the microwave ovens tested under the disapproved testing program,
2. introducing or importing microwave ovens into U.S. commerce which bear false and misleading certification, that is, microwave ovens certified under the testing program which have been disapproved, and
3. introducing or importing into U.S. commerce any microwave oven which does not have the certification label permanently affixed to the product, as required by 21 CFR § 1010.2.

Under Section 536(a) of the Act, FDA may refuse entry or importation into U.S. commerce of any electronic product if it appears that the product fails to comply with the applicable standards, or the manufacturer’s testing program has been disapproved. Therefore, Tatung Wu-Jiang microwave oven factory is being placed on the import detention list and its microwave ovens will be automatically detained at port of entry until the quality control and testing program disapproval is rescinded.

The FDA may initiate regulatory action against any person who violates Section 538 of the Act, including seeking an injunction and/or imposition of civil penalties as provided for in Section 539 of the Act. Persons failing to correct violations are subject to civil penalties of up to \$1,000 per violation and up to a maximum of \$300,000. Section 538 of the Act also prohibits anyone, including the importer, from failing to make any report required pursuant to Section 537(b) or to furnish or preserve any information required pursuant to Section 537(f).

Under 21 CFR § 1005.21 and Section 536 of the Act, the manufacturer shall have an opportunity to present views and evidence that the products comply with the Federal Performance Standard for Microwave Ovens, 21 CFR 1030.10, and that the testing program is adequate to assure the compliance of all microwave ovens.

Inspection Findings

On March 11, 2003, Mr. Joseph C. Teixeira and Ms. Dawn M. Braswell from the FDA conducted a pre-announced inspection of Tatung Wu-Jiang microwave oven factory. The purpose of this inspection was to review your quality control and testing program for the

certification of compliance of microwave ovens with the U.S. Federal Performance Standard for Microwave Ovens, 21 CFR §1030.10. This inspection involved reviewing the quality control and testing procedures, including incoming component inspection of critical parts, production line assembling, electrical testing of safety interlocks and monitor, repair procedures, final microwave radiation emission testing procedures, labeling procedures, audit procedures, record-keeping, door cycle endurance testing, maintenance and calibration checks of the compliance microwave survey instruments. Before the inspection started, the FDA inspectors were informed by Tatung Wu-Jiang management that there was no production of U.S. made ovens because of “vendor quality problems.” Since no procedures could be observed on the production line, the FDA inspectors requested a demonstration of final quality control checks and microwave emission testing on a sample microwave oven taken from warehouse stock. Other areas of the factory such as maintenance and calibration of microwave survey instruments, incoming component inspection, test records, etc., were observed. The FDA inspectors reported the following deficiencies in complying with the applicable performance standard (21 C.F.R. § 1030.10) and with Tatung Wu-Jiang's quality control and testing program for microwave ovens:

1. Microwave emission tests were not performed correctly. For example,
 - a. The technician did not scan all the back vents. When the FDA investigator demonstrated the correct scan of the oven, he found excessive microwave emission emanating from the back vent greater than \bullet mW/cm². The factory's written quality control and testing procedures require the back vents be scanned. Excessive microwave emission from the back vents may be indicative that the magnetron was not properly installed on the production line.
 - b. The technician was incorrectly scanning the bottom of the door seal. The oven was placed six inches from the edge of the test bench where it was not possible to scan the bottom edge of the door seal. When the FDA investigators demonstrated the proper way of scanning the bottom door seal, they found two spots along the door seal (one of which was on the bottom) that exceeded the factory reject limit of \bullet mW/cm².
 - c. The technician was scanning too fast, greater than the specified maximum 2.5 cm/sec rate. A scan rate of no more than 2.5 cm/sec is necessary to account for the slow modulation leakage caused by the turntable in the oven and to allow for the response time of the compliance microwave survey instruments.
 - d. The technician unnecessarily scanned solid areas on the outside cabinet of the oven where there are no openings and there is no possibility of microwave energy emissions.

2. The maintenance and calibration of microwave compliance survey instruments were not performed properly in accordance to established procedures. For example,
 - a. The Local Calibration Reference (LCR) Holaday meter, HI-1700, was beyond its scheduled calibration date. The LCR is used to set up the initial reference field in the calibration constancy intercomparison system. This system is used to ensure the proper function and calibration constancy of the compliance microwave survey instruments. The LCR must be calibrated periodically (at least annually).
 - b. Daily checks were not performed on the compliance microwave survey instruments as required in CDRH's established procedures.
 - c. A dirty spacer cone was observed on one of the compliance microwave survey meter probes. Measurement accuracy will be affected by contamination of particles imbedded in the cone.
3. Final quality control test records contained whiteouts and overwrites. No whiteouts should be used to correct the mistakes on the final test records. Errors should be corrected by drawing a single line through such an error, then recording the correct data next to it and initialed by the technician.

Conclusion

The above deficiencies have been brought to the attention of Tatung Wu-Jiang's quality control and testing personnel. We are also comparing these deficiencies with your March 17, 2003, "FDA Audit Correction Report," listing your corrective action responses to FDA 483 items presented during the inspection. Some corrective action steps are outlined in your March 17, 2003 response, but additional documentation must be submitted to this office to demonstrate that those actions have been taken.

To resolve this matter, you must submit a written response to each item listed in the Inspection Findings section of this letter such that 1) CDRH can determine that Tatung Wu-Jiang is in compliance with the Act, 2) the subject products comply with the Federal Performance Standard for Microwave Ovens, 21 CFR 1030.10, 3) the testing program is in accord with good manufacturing practices. Tatung Wu-Jiang must also, under 21 CFR 1002.10, submit to CDRH an updated quality control report for all active model families. This report must contain all of the corrective actions in response to the deficiencies cited in this Warning letter. In addition, CDRH may require other information reasonably necessary to establish that the products comply with the standard and to enable CDRH to carry out the purposes of the Act. Under 21 CFR 1002.10(k), CDRH requests the following additional information:

1. Tatung Wu-Jiang's quality control and testing program for microwave ovens must be inspected by an independent consultant or a firm who will observe the actual quality control and testing procedures and compare them with those reported in the up-dated quality control product report. The inspection should include the following: incoming inspection and control of critical components, metal and welding fabrication, weld testing, critical inspection of the doors and cavities by the quality control department, production line assembly including magnetron installation, testing of safety interlocks and monitor, door open start test, final microwave emission testing, audit, repair, record-keeping, door endurance cycle test, instrumentation and calibration of microwave survey instruments (daily and monthly checks, sending broken meters out for repair and calibration). This independent inspection report should be furnished along with any response concerning this program disapproval. Please note that our office cannot make any recommendation or endorse any consultant for this independent inspection.
2. Tatung Wu-Jiang is to provide CDRH with a video of the final microwave oven emission testing procedures, audit testing procedures and microwave survey instrument calibration check procedures. This video should be in NTSC VHS, DVD, or VCD format. The audio portion of the video must be in English.
3. From the deficiencies reported in this factory, it is clearly evident that there is a need for a periodic training program to ensure that all personnel, including supervisors, quality control and testing personnel, adequately perform their assigned responsibilities and learn how particular job functions relate to the overall quality system. This training program should cover the consequences of improper performance so that personnel know what to look for, as well as be aware of the effect their actions can have on the radiation safety of the product. A copy of the final training report should be translated to English for our review. We recommend that the same consultant hired to perform the independent inspection review the training report for completeness and accuracy before submitting it to CDRH.
4. Also, there appears to be a lack of supervision in critical areas of the quality control and testing program. Your up-dated quality and control testing program should require the supervisors to periodically observe quality control and test personnel to ensure that they are doing their tasks correctly such as double checking their records, checking that final testing operators are scanning at the correct scan speed of no more than 2.5 cm/sec, scanning the surfaces correctly, and so on.
5. We recommend that an annual internal audit be set up to assure that the quality system requirements are being met and to determine the effectiveness of the quality system. We recommend that the quality audit be conducted by a qualified individual

who does not have direct responsibility for the matters being audited. Please describe how this annual audit will be conducted, who will do it and when. CDRH recommends that after the disapproval of the testing program is rescinded, the company be audited twice during the first 12 months and then annually afterwards if no major problems are found for a period of 3 years.

6. Pursuant to 21 CFR 1003.11(b), you are requested to provide CDRH with the total number of microwave ovens that have been produced and the approximate number of such products which have been shipped to the U.S. since June 30, 2002, the date of the last reporting period.

The CDRH will advise you whether your submittal is satisfactory and when introduction of certified microwave ovens into U.S. commerce may resume from the Tatung Wu-Jiang microwave oven factory. A copy of this letter will be posted on the FDA's World Wide Web home page under Monthly Import Detention List and Warning Letters:
<http://www.fda.gov>.

Within 15 days, please submit your response to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, (HFZ-342), Division of Enforcement B, 2098 Gaither Road, Rockville, Maryland 20850. In your response, please reference case I1- 1945. If you have any questions, you may contact Mr. George Kraus of my staff at (301) 594-4654, by facsimile at (301) 594-4672, or by electronic mail at gwk@cdrh.fda.gov.

Sincerely yours,



for Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure: Copy of FDA 483 Inspectional Observations
Copy of Establishment Inspection Report